

STOOL SOFTENER AND STIMULANT LAXATIVE- docusate sodium and sennosides capsule, gelatin coated
Cardinal Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Stool Softener + Stimulant Laxative

DRUG FACTS

Purpose

Stool softener
Stimulant Laxative

**Active ingredients
(in each softgel)**

Docusate sodium 50 mg
Sennosides 8.6 mg

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6-12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless told to do so by a doctor
- if you are presently taking mineral oil, unless told to do so by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use of a laxative. These may indicate a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1800-222-1222) right away.

Directions

- Take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses

adults and children 12 years of age or over
children 6 to under 12 years of age
children 2 to under 6 years of age
children under 2

take 2-4 softgels daily
take 1-2 softgels daily
take upto 1 softgel daily
ask a doctor

Other information

- **each softgel contains:** calcium 2 mg and sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- Keep tightly closed

Inactive ingredients

Aerosil, beeswax, FD&C Red No.33, FD&C Red No.40, gelatin, glycerin, light liquid paraffin, povidone (PVP K-30), purified water, sodium carboxymethylcellulose, sorbitol solution, soya lecithin, titanium dioxide

Questions or Comments?

1-888-333-9792

*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Colace® 2-IN-1.

© 2019 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Made in India

All LEADER™ Brand Products Have A
Return to place of purchase if not satisfied.
100% Money Back Guarantee

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY
SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION

PRINCIPAL DISPLAY PANEL - 60 Capsule Bottle Carton

Leader™

NDC 70000-0442-1

Stool
Softener +

Stimulant
Laxative

Docusate Sodium, 50 mg
Sennosides, 8.6 mg

COMPARE TO
COLACE®
2-IN-1
active ingredients*

100% Money
Back Guarantee

60 SOFTGELS

Actual Size



STOOL SOFTENER AND STIMULANT LAXATIVE

docusate sodium and sennosides capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0442
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Product Characteristics

Color	red (OPAQUE)	Score	no score
Shape	CAPSULE (SOFTGEL)	Size	12mm
Flavor		Imprint Code	584
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0442-1	1 in 1 CARTON	01/30/2019	
1		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/30/2019	

Labeler - Cardinal Health (063997360)

Revised: 11/2021

Cardinal Health